

### **REMARKS**

Reconsideration is respectfully requested in view of the amendments and remarks herein.

#### **Discussion of the Amendments to the Claims**

The claims have been amended to more particularly point out and to more distinctly claim the subject matter of the present invention. In particular, claims 1-2, 5, and 6 have been amended herein to indicate the L-configuration on the stereocenter lysine.

#### **Response to the Rejection under 35 U.S.C. § 112, 1<sup>st</sup> Paragraph**

Claims 1-2, 5-7, and 15 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner has alleged that “[o]ne of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises any racemate or enantiomer of the peptide of Formula I”. (Office Action, page 4).

Reconsideration is respectfully requested in view of the amendments and remarks herein.

As noted above, claims 1-2, 5, and 6 have been amended herein to indicate the L-configuration on the stereocenter lysine. It is respectfully submitted that the amendments to claims 1-2, 5, and 6 obviate the basis for the rejection with regard to those claims, as well as the rejection with regard to claims 7 and 15.

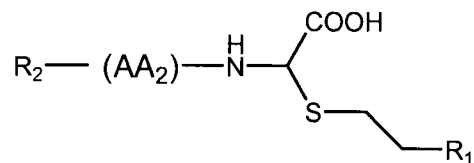
Moreover, Applicants respectfully submit that the examples in the application provide ample support for the phrase “as racemated or as enantiomeric pure isomers” in claim 1. In particular, Applicants respectfully point out that the examples disclosed in the description include compounds which exhibit the D/L-configuration on the substituted glycine stereocenter.

Accordingly, it is respectfully submitted that the phrase “as racemated or as enantiomeric pure isomers” in claim 1 is fully supported by the present application and is allowable, the enantiomeric pure compounds being also present in racemic mixtures.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

**Response to the “Claim Observations”**

Claim 1 of the present application as presented herein recites compounds of general formula I



wherein

R<sub>1</sub> means a CH<sub>2</sub>NH<sub>2</sub> or NHC(NH)NH<sub>2</sub> group,

AA<sub>2</sub> means non-substituted or substituted L-lysine, wherein the substituents are common protective groups, and

R<sub>2</sub> means a Bz, Bzl, Ac, Boc, Z, Suc, MeoSuc or Tos group,

provided that the following cases do not occur simultaneously: R<sub>1</sub> = NHC(NH)NH<sub>2</sub>, R<sub>2</sub> = Z and

(AA<sub>2</sub>) = non-substituted or Boc-substituted L-lysine,

as racemated or as enantiomeric pure isomers,

and the salts thereof with mineral or organic acids.

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Applicants wish to point out for the record that the compound of Hong et al. corresponds to the compound excluded by the proviso of claim 1 (both as previously presented and as presented herein). In particular,

“provided that the following cases do not occur simultaneously:  $R_1 = \text{NHC}(\text{NH})\text{NH}_2$ ,  $R_2 = \text{Z}$  and  $(\text{AA}_2) = \text{non-substituted or Boc-substituted lysine, . . .}$ ”

corresponds to:

N6-[(1, 1-dimethylethoxy)carbonyl]-N2-[(phenylmethoxy)carbonyl]-L-lysyl-2-[[2-[(aminoiminomethyl)amino]ethyl]thio]-(2S)-Glycine”.

Moreover, in response to the Examiner’s comments, Applicants wish to point out, for the record, that the compounds of the present application are dipeptides in which, however, the substituted glycine does not represent a naturally occurring amino acid.

### **Concluding Remarks**

Applicants have responded in full to the present Office Action. Favorable action thereon is respectfully solicited.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. §1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. §1.136.

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Should the Examiner have any questions or comments concerning this Response to Office Communication, the Examiner is respectfully invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Andrea M. Wilkovich

Registration No.: 53,773

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(973) 331-1700